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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,330	05/04/2001	Koji Fujimoto	Q64378	7377

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07/31/2003

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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

6

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,330

Applicant(s)

FUJIMOTO

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caveney et al.

Caveney et al teaches a pipetter/diluter method in which the system is first primed by drawing reagent (or diluent or buffer, col. 5, line 5) into the system and flushing it out through the hand probe (instant pipette tip). Then sample and/or reagent is aspirated and dispensed, and the system may be flushed with reagent (or diluent or buffer) flowing out of the tip. See, e.g., col. 10, lines 44-65. Multiple reagents can be used (col. 12, line 67). Complicated sequences of aspirating, dispensing and washing may be performed (col. 3, lines 30-50).

Caveney fails to explicitly teach dispensing into a mixing cell.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a mixing cell, such as a test tube to receive the products dispensed as taught by Caveney (col. 12, lines 36-37). Note that the reagent or diluent vessel on the far left of figure 10 corresponds to the liquid cell. With respect to claim 8, it would have been obvious provide both a reagent and a diluent to the vessel in order to use a dilute reagent. With respect to claims 18 and 20, it would have been obvious to provide separate reagent and/or diluent vessels (instant liquid cells) in order to provide multiple reagents as taught by Caveney at col. 12, line 67. With respect to the various aspiration, dispensing and washing steps claimed, it would have been obvious to combine the steps taught by Caveney into complex sequences for use in analysis as taught by Caveney. With respect to claims 22 and 23, Caveney teaches that the probe tip (instant pipette tip) is tapered to minimize sample carryover and does not teach changing the tip; therefore it would have been obvious to use the same probe tip in all the dispensing portions of the pipetting steps.

4. Applicant's arguments filed May 19, 2003 have been fully considered but they are not persuasive.

5. Applicant argues that Caveney does not teach washing the tip with the liquid remaining in the cell, but Caveney teaches that after dispensing, the system can be washed by passing reagent (which would have remained in the "liquid cell," having not been drawn into the system during the metering of a defined portion of reagent used previously) through the tip. See, e.g., col. 10, lines 49-65. Note that the claims do not require immersion of the tip in the liquid cell or washing of an exterior surface of the tip.

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6. Applicant argues that Caveney provides different sucking and discharging openings, whereas in the instant invention, pipetting, i.e., sucking and discharging, is carried out using the same tip. This argument is not persuasive because there is no limitation to sucking and discharging using the same tip. Further, the claims do not preclude a second entrance to the pipetting tube. The claims merely require, e.g. as in claim 1, "pipetting a portion of the specimen and a portion of the liquid...using a pipetting tip". The sample is aspirated and dispensed through the probe tip (instant pipetting tip), and the reagent/diluent is aspirated through a second opening submerged in the liquid cell and dispensed using the probe tip (instant pipetting tip). Thus, the sample is pipetted using a pipetting tip and the reagent/diluent is pipetted using a second opening and the same pipetting tip (the probe tip). Thus, the sample and reagent/diluent are pipetted using the same pipetting tip, albeit also using the second opening, not precluded in the instant claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
July 24, 2003